

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ )  
FENFLURAMINE/DEXFENFLURAMINE) ) MDL NO. 1203  
PRODUCTS LIABILITY LITIGATION )  
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THIS DOCUMENT RELATES TO: )  
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SHEILA BROWN, et al. ) CIVIL ACTION NO. 99-20593  
 )  
 v. )  
 )  
AMERICAN HOME PRODUCTS ) 2:16 MD 1203  
CORPORATION )

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9226

Bartle, J.

April 15, 2014

The Estate of Dennis J. Kennedy ("Estate"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Patti Kennedy, the spouse of Dennis J. Kennedy ("Mr. Kennedy"), also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify Diet Drug Recipients for compensation purposes based upon the severity of (continued...)

To seek Matrix Benefits, a representative claimant<sup>4</sup> must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the Diet Drug Recipient's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In December, 2011, Patti Kennedy, the personal representative of the Estate, submitted a completed Green Form to the Trust signed by the attesting physician, Manoj R. Muttreja, M.D. Based on an echocardiogram dated February 7, 2002, Dr. Muttreja attested in Part II of the Green Form that

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3. (...continued)

their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients were diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs, or beneficiaries. See Settlement Agreement § II.B.

Mr. Kennedy suffered from mild aortic regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™. Based on such findings, the Estate would be entitled to Matrix A-1, Level III benefits in the amount of \$859,612.<sup>5</sup>

Dr. Muttreja also attested in the Green Form that Mr. Kennedy did not suffer from congenital aortic valve abnormalities. Under the Settlement Agreement, the presence of congenital aortic valve abnormalities, specifically, "unicuspid, bicuspid or quadricuspid aortic valve[s], [or] ventricular septal defect associated with aortic regurgitation," requires the payment of reduced Matrix Benefits. Settlement Agreement § IV.B.2.d.(2)(c)i)a). As the Trust does not contest the Estate's entitlement to Level III benefits, the only issue before us is whether the Estate is entitled to payment on Matrix A-1 or Matrix B-1.

The Trust forwarded the claim for review by Rohit J. Parmar, M.D., F.A.C.C., one of its auditing cardiologists.<sup>6</sup> In

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5. Under the Settlement Agreement, a representative claimant is entitled to Level III benefits if the Diet Drug Recipient suffered from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

6. The Estate's claim was originally audited in March, 2012 by Robert Gillespie, M.D., one of the Trust's auditing cardiologists. In audit, Dr. Gillespie determined that there was no reasonable medical basis for the attesting physician's finding that Mr. Kennedy did not have a congenital aortic valve

(continued...)

audit, Dr. Parmar concluded that there was no reasonable medical basis for Dr. Muttreja's representation that Mr. Kennedy did not have a congenital aortic valve abnormality. Dr. Parmar explained:

The aortic valve is a bicuspid aortic valve with associated aortic valve stenosis and aortic regurgitation. The bicuspid aortic valve is identified at pathology. Please see the pathology report which states "Bicuspid aortic valve with aortic stenosis."<sup>7</sup>

Based on Dr. Parmar's finding that Mr. Kennedy had a congenital aortic valve abnormality, the Trust issued a post-audit determination that the Estate was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.<sup>8</sup> In contest, the Estate

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6. (...continued)

abnormality. The Estate's claim was subjected to re-audit pursuant to Court Approved Procedure No. 11.

7. Dr. Parmar also determined that there was no reasonable medical basis for the attesting physician's finding that Mr. Kennedy did not have aortic stenosis as defined by the Settlement Agreement. Under the Settlement Agreement, the presence of aortic stenosis also requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)c. Given our disposition with respect to Mr. Kennedy's congenital aortic valve abnormality, we need not address this issue.

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

argued that Dr. Parmar inappropriately relied solely on the pathology report for Mr. Kennedy's aortic valve surgery and, in doing so, "disregarded the instructions that are found in Part II of the Green Form." The Estate contended that the Green Form required a review of an echocardiogram, a cardiac catheterization, or surgical examination to determine the presence of a specific medical condition.<sup>9</sup> Accordingly, the Estate asserted that it was entitled to Matrix A-1 benefits because the auditing cardiologist did not find echocardiographic evidence of a congenitally bicuspid valve and the surgeon stated that Mr. Kennedy's aortic valve was "trileaflet."<sup>10</sup>

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Parmar submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that Mr. Kennedy did not have a congenital aortic valve abnormality. Dr. Parmar stated, in pertinent part:

9. In accordance with the Trust's request, I reviewed the Claim and Claimant's Contest Materials. Both a bicuspid

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9. The Estate also asserted that "[m]ost likely, the [auditing cardiologist] withheld the echocardiographic evidence of a tricuspid aortic valve, because such evidence was favorable to the [Estate]."<sup>11</sup> The Estate does not provide any support for this assertion.

10. The Estate also argued that a claim cannot be reduced to the B Matrix unless the condition was diagnosed between the commencement of Diet Drug use and the end of the Screening Period. We have rejected this argument. See, e.g., PTO No. 8822, at 9-12 (Feb. 22, 2012), aff'd, 525 F. App'x 140 (3d Cir. 2013).

aortic valve and Aortic Stenosis are clearly seen on the March 28, 2007 [transesophageal echocardiogram] submitted at Contest. The [transesophageal echocardiogram] at 10:49 confirms the presence of a bicuspid aortic valve. While bicuspid aortic valve is not noted on the [transesophageal echocardiogram] report, it is clearly evident from review of the study....

10. At Contest, I also re-reviewed the February 7, 2002 echocardiogram of attestation, as well as Claimant's March 5, 2007 [transthoracic echocardiogram] and March 9, 2007 cardiac catheterization study.... The March 5, 2007 [transthoracic echocardiogram] is of reasonable quality but not enough for me to determine whether there is a bicuspid or a tricuspid aortic valve, nor can I determine the nature of the aortic valve on the March 9, 2007 cardiac catheterization study.
11. Based on my review, I confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's representations that Claimant did not have congenital aortic valve abnormalities or Aortic Stenosis. Claimant had a bicuspid aortic valve, which is evident on the March 28, 2007 [transesophageal echocardiogram] and noted on the Pathology Report....

The Trust then issued a final post-audit determination, again determining that the Estate was entitled only to Matrix B-1, Level III benefits. The Estate disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

show cause why this claim should be paid. On January 25, 2013, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8997 (Jan. 25, 2013).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on March 28, 2013, and the Estate submitted a sur-reply on April 18, 2013. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>11</sup> to review claims after the Trust and the representative claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and the Estate and to prepare a report for the court.<sup>12</sup> The Show Cause

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11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

12. The Estate filed Objections to the Special Master's Order Referring Claim to a Technical Advisor for Review and Motion to Close Show Cause Record. We previously have recognized that it is within our discretion to appoint a technical advisor, particularly where, as here, there are conflicting expert opinions at issue. See, e.g., Mem. in Supp. of PTO 9077 (May 29, 2013). Thus, we will overrule the Estate's objections  
(continued...)

Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether the Estate has met its burden of proving that there is a reasonable medical basis for the attesting physician's finding that Mr. Kennedy did not have a congenital aortic valve abnormality. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in the Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of its claim, the Estate reasserts the arguments made in contest. The Estate also argues that the reasonable medical basis standard requires that deference be given to the conclusions of the attesting physician. In addition, the Estate contends that, because the auditing cardiologist did not find evidence of a bicuspid aortic valve on Mr. Kennedy's February 7, 2002 echocardiogram, the bicuspid valve was not "congenital" as required by the Settlement Agreement.

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12. (...continued)  
and deny its motion to close the Show Cause Record.

The Estate also submitted a declaration of Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C., F.A.H.A., who stated, in pertinent part:

2. I reviewed the 3/28/07 [transesophageal echocardiogram] disc and the 11/29/12 Declaration of Rohit Parmar, M.D.

3. In his declaration, Dr. Parmar alleged that a bicuspid aortic valve is "clearly" seen on the 3/28/07 [transesophageal echocardiogram]. He further alleged that the [transesophageal echocardiogram] confirms the presence of a bicuspid aortic valve at 10:49. These opinions are incorrect.

- a) There is no evidence of a bicuspid aortic valve on this study.
- b) There is no image whatsoever identified at time stamp 10:49.

4. A normal aortic valve (AoV), in cross-sectional views, has three cusps which meet in the middle, such that the lines of apposition form a "Mercedes Benz" sign, readily seen on echocardiogram.

In this case, image loops 28, 29 (and to a lesser quality 39) are cross-sections of the [aortic valve]. These cross-sectional views clearly show the presence of three cusps. The cusps are thickened and two may be partially fused, thus rendering the appearance of a "bicuspid" valve.... However, on closure they produce the tri-partite "Mercedes Benz" sign, which confirms the presence of a congenitally normal tricuspid [aortic valve].<sup>13</sup>

Finally, the Estate asserts that the Settlement Agreement and the Seventh Amendment to the Settlement Agreement "guaranteed class members certain benefits related to valve surgery."

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13. Dr. Dlabal also attached three still frame images from the echocardiogram, which purportedly demonstrate a tricuspid aortic valve.

In response, the Trust argues that the Estate has not established a reasonable medical basis for Dr. Muttreja's representation that Mr. Kennedy did not have a congenital aortic valve abnormality. In addition, the Trust asserts that it properly applied the reasonable medical basis standard.

The Technical Advisor, Dr. Vigilante, reviewed the echocardiograms dated February 7, 2002; March 5, 2007; and March 28, 2007 and concluded that there was no reasonable medical basis for the attesting physician's finding that Mr. Kennedy did not have a congenital aortic valve abnormality. As to the February 7, 2002 echocardiogram, Dr. Vigilante stated, in pertinent part:

As noted at time frame 00:25 of the study, the aortic leaflets did not close in the mid line which is suggestive of a bicuspid aortic valve. At time 2:59 on this tape, the parasternal short-axis view demonstrated calcification and fusion of the right and left coronary leaflets with a raphe and poor motion. Only the non-coronary leaflet moved adequately. This study was diagnostic of a congenital bicuspid aortic valve.

As to the March 5, 2007 echocardiogram, Dr. Vigilante observed that, "In the parasternal long-axis view, the [aortic] valve did not close in the middle axis with a congenital bicuspid aortic valve noted." As to the March 28, 2007 echocardiogram, Dr. Vigilante explained, in pertinent part:

Evaluation of the aortic valve demonstrated this to be an obvious congenital bicuspid valve with congenital fusion of the left and right coronary leaflets. There was a raphe noted between these two leaflets.... This congenital bicuspid valve was obvious in real

time loops 10, 11, 12, 13, 28, 29, 30, and 43.... It should be noted that Dr. Dlabal is wrong when he stated that there was no evidence of a bicuspid aortic valve on this study. Indeed, the three screen shots submitted by Dr. Dlabal clearly show a bicuspid aortic valve with a raphe between the right and left coronary leaflets classic for a congenitally bicuspid aortic valve.

In response to the Technical Advisor Report,<sup>14</sup> the Estate argues that the Technical Advisor substituted his own opinion for that of Mr. Kennedy's cardiologists and that he did not consider all of the relevant evidence, including evidence supportive of the Estate's arguments.<sup>15</sup>

After reviewing the entire Show Cause Record, we find the Estate's arguments are without merit. As noted, the Settlement Agreement requires that a claim for Level III Matrix

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14. The Estate initially included with its response to the Technical Advisor Report verified "rebuttals" by Dr. Muttreja and Dr. Dlabal. Pursuant to Audit Rule 34, the Special Master determined these rebuttals could not become part of the Show Cause Record. Thereafter, the Estate filed "objections" to the decision denying the inclusion of these rebuttals in the Show Cause Record and a motion to have them included. According to the Estate, in their rebuttals, Dr. Muttreja and Dr. Dlabal disputed the Technical Advisor's finding of congenital aortic valve abnormality. Pursuant to Audit Rule 34, there is no procedure by which Dr. Muttreja's and Dr. Dlabal's supplemental declarations can become part of the Show Cause Record. See, e.g., Mem. in Supp. of PTO No. 9041, at 9 n.11 (Apr. 5, 2013); Mem. in Supp. of PTO No. 8402, at 12 n.13 (Feb. 22, 2010). For these reasons, we overrule claimant's objections and deny its motion.

15. In particular, the Estate asserts that Dr. Vigilante failed to consider the observations of Mr. Kennedy's surgeon. Contrary to the Estate's argument, the Technical Advisor Report reflects that Dr. Vigilante did consider the separate report related to Mr. Kennedy's aortic valve surgery.

Benefits based on damage to the aortic valve be reduced to the B Matrix if the Diet Drug Recipient had a congenital aortic valve abnormality, such as a bicuspid valve. See Settlement Agreement § IV.B.2.d.(2)(c)i)a). According to claimant, there is a reasonable medical basis for finding Mr. Kennedy did not have a congenital aortic valve because Dr. Dlabal found that Mr. Kennedy's March 28, 2007 echocardiogram did not show a bicuspid aortic valve.

Dr. Parmar, however, reviewed the March 28, 2007 echocardiogram and determined that it demonstrated a bicuspid aortic valve.<sup>16</sup> In addition, Dr. Vigilante reviewed the March 28, 2007 echocardiogram and concluded it "to be an obvious congenital bicuspid valve with congenital fusion of the left and right coronary leaflets." Dr. Vigilante also observed that "the three screen shots submitted by Dr. Dlabal clearly show a bicuspid aortic valve with a raphe between the right and left coronary leaflets classic for a congenitally bicuspid aortic valve."<sup>17</sup>

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16. We also reject the Estate's assertion that the auditing physician never concluded that Mr. Kennedy had a "congenital" aortic valve abnormality. Dr. Parmar's declaration makes clear that he concluded there was no reasonable medical basis for the attesting physician's finding that Mr. Kennedy did not have a congenital aortic valve abnormality and he specifically noted that Mr. Kennedy's aortic valve was bicuspid, which constitutes a congenital aortic valve abnormality under the Settlement Agreement. See Settlement Agreement § IV.B.2.d.(2)(c)i)a).

17. For these reasons as well, we disagree with the Estate that the reasonable medical basis standard requires that deference be  
(continued...)

Significantly, although the Estate argued that Mr. Kennedy's valve could not have been "congenital" unless it was present on the February 7, 2002 and March 5, 2007 echocardiograms, the Estate's physicians did not specifically address these echocardiograms. As to these echocardiograms, the Estate relies only on the echocardiogram reports. These reports, however, do not establish that Mr. Kennedy did not have a bicuspid aortic valve. In fact, neither report states that Mr. Kennedy's aortic valve was normal or trileaflet. In addition, Dr. Vigilante reviewed these two echocardiograms and concluded that both studies were diagnostic of a bicuspid aortic valve.<sup>18</sup>

In addition, the Estate's argument that the pathology report, which specifically notes in the "Final Diagnosis" that Mr. Kennedy had a "[c]ongenitally bicuspid aortic valve with fibrosis," should be disregarded because the presence of a congenital aortic valve abnormality only can be determined through echocardiographic evidence or surgical examination is misplaced.<sup>19</sup> The Settlement Agreement identifies certain

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17. (...continued)  
given to the conclusions of the attesting physician.

18. Contrary to the Estate's argument, the Technical Advisor's findings are not "erroneous" simply because the auditing cardiologist did not determine whether the February 7, 2002 echocardiogram demonstrated the presence of a bicuspid aortic valve and could not determine the presence of a bicuspid aortic valve on the March 5, 2007 echocardiogram.

19. While the Estate asserts that the pathologist only agreed that Mr. Kennedy's aortic valve was "functionally" bicuspid, this ignores the "Final Diagnosis," which specifically states that  
(continued...)

reduction factors that are only applicable when there is echocardiographic evidence of the condition. See e.g., Settlement Agreement § IV.B.2.d.(2)(c)ii)e) (rheumatic mitral valve); § I.39 (mitral valve prolapse). As nothing in the Settlement Agreement limits application of the reduction factor of congenital aortic valve abnormalities to those that are present based solely on a review of an echocardiogram, a cardiac catheterization, or surgical examination, we decline the Estate's request to impose this limitation. In any event, Dr. Parmar and Dr. Vigilante each found echocardiographic evidence of a bicuspid aortic valve.<sup>20</sup>

Finally, we do not agree that the Estate is entitled to Matrix A-1, Level III benefits under the Seventh Amendment. As an initial matter, the Seventh Amendment specifically states, "The determinations and actions of the Trust on any aspect of a claim for Cash/Medical Services Benefits of a Category One Class Member or Category Two Class Member, or on any claim for the Matrix Election Payment, shall have no preclusive or precedential effect of any kind on the Trust in the administration ... of

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19. (...continued)

Mr. Kennedy's aortic valve was "congenitally" bicuspid, not "functionally" bicuspid.

20. For this reason, and because no other medical record in this case reflects Mr. Kennedy had a tricuspid aortic valve, the surgeon's isolated statement that Mr. Kennedy's aortic valve was tricuspid does not satisfy the Estate's burden.

claims for Seventh Amendment Matrix Compensation Benefits."<sup>21</sup> Seventh Amendment § IX.E. The Seventh Amendment further provides that:

For each Category One Class Member or Category Two Class Member found to be eligible for Seventh Amendment Matrix Compensation Benefits, the Trust shall calculate as a Net Matrix Amount, a sum equal to the gross amount payable to the Diet Drug Recipient or Representative Claimant and their associated Derivative Claimants, if any, on the applicable Matrix under section IV.B.2 of the Settlement Agreement ....

Id. § IX.A.2. (emphasis added). Section IV.B.2.d. sets forth "[t]he circumstances which determine whether Matrix A-1 or Matrix B-1 is applicable ...." Settlement Agreement § IV.B.2.d. As the Estate has not established a reasonable medical basis for finding that Mr. Kennedy did not have a congenital aortic valve abnormality, the Settlement Agreement requires that the Estate's Level III claim be reduced to the B Matrix.

Therefore, we will affirm the Trust's denial of the Estate's claim for Matrix A-1 benefits and the related derivative claim submitted by Mr. Kennedy's spouse, Patti Kennedy.

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21. Under the Seventh Amendment, Seventh Amendment Matrix Compensation Benefits means "those Matrix Compensation Benefits which may be paid or claimed for High Matrix Level Qualifying Factors to or by Category One Class Members or Category Two Class Members in accordance with the terms of the Seventh Amendment." Seventh Amendment § I.64. The Estate is a Category Two Class Member, and its claim for Level III Matrix Benefits is a claim for Seventh Amendment Matrix Compensation Benefits.